L ISA R. Y ANEK , MPH ■ D IANE M. B ECKER , S C D MPH

T ARYN F. M OY , MS RD ■ J OEL G ITTELSOHN , P H D

D YANN M ATSON K OFFMAN , D R PH MPH CHES

Project Joy: Faith Based Cardiovascular Health Promotion for African American Women

Ms. Yanek, Dr. Becker, and Ms. Moy are
with the Center for Health Promotion,
Johns Hopkins University School of
Medicine, Baltimore, Maryland. Ms. Yanek
and Ms. Moy are Research Associates; Dr.
Becker is a Professor of Medicine. Dr.
Gittelsohn is an Associate Professor,
International Health, Johns Hopkins
University Bloomberg School of Public
Health. Dr. Koffman is a Project Officer
with the National Center for Chronic
Disease Prevention and Health
Promotion, Centers for Disease Control
and Prevention, Atlanta, Georgia.

SYNOPSIS

Objective. The authors tested the impact on cardiovascular risk profiles of African American women ages 40 years and older after one year of participation in one of three church-based nutrition and physical activity strategies: a standard behavioral group intervention, the standard intervention supplemented with spiritual strategies, or self-help strategies.

Methods. Women were screened at baseline and after one year of participation. The authors analyzed intention-to-treat within group and between groups using a generalized estimating equations adjustment for intra-church clustering. Because spiritual strategies were added to the standard intervention by participants themselves, the results from both active groups were similar and, thus, combined for comparisons with the self-help group.

Results. A total of 529 women from 16 churches enrolled. Intervention participants exhibited significant improvements in body weight (-1.1 lbs), waist circumference (-0.66 inches), systolic blood pressure (-1.6 mmHg), dietary energy (-117 kcal), dietary total fat (-8 g), and sodium intake (-145 mg). The self-help group did not. In the active intervention group, women in the top decile for weight loss at one year had even larger, clinically meaningful changes in risk outcomes (-19.8 lbs).

Conclusions. Intervention participants achieved clinically important improvements in cardiovascular disease risk profiles one year after program initiation, which did not occur in the self-help group. Church-based interventions can significantly benefit the cardiovascular health of African American women.

Address correspondence to:
Ms. Yanek, Johns Hopkins University Center for Health Promotion, Room 8024, 1830 E. Monument St., Baltimore MD
21205; tel. 410-955-7671; fax 410-955-0321; e-mail <lryanek@welch.jhu.edu>.

Urban African American women aged 40 years and older bear a marked excess risk of obesity, sedentary lifestyle, and attendant cardiovascular disease (CVD) morbidity and mortality. Public health strategies to lower the risk of lifestyle-related cardiovascular disease in this group have met with little long-term success.[1]

In African American communities, the church community remains the primary source of social support and community leadership, particularly among older African American women.[2,3] Churches are well-accepted sites for cancer screening,[4,5] blood pressure control,[6,7] weight loss programs,[6-8] cholesterol education,[7,9] smoking cessation,[7,10,11] diabetes education,[8] stroke prevention,[12] physical activity,[6,7,13] and nutrition education.[14] However, evaluation of these programs for long-term results has been sparse, and health promotion activities that are integrated into church culture have not been tested previously in the African American community.

Project Joy was designed to address the need for well-evaluated, culturally integrated programs focusing on lifestyle change in African American women. Participants in the pilot project named the program from a Bible verse, "...for the Joy of the Lord is your strength" (*Nehemiah 8:10b*). Project Joy was designed to test several strategies in the church environment to reduce cardiovascular risk in urban communities where most African American women are regular churchgoers.[15,16] The overall objective was to determine the impact of active nutrition and physical activity interventions on one-year measures relating to lifestyle risk factors and CVD risk profiles compared with a self-help (control) group. The study was also designed to determine the extent to which a strong spiritual component and elements of church culture strengthen the impact of standard behavioral group interventions in the church.

METHODS

This study was approved by the Johns Hopkins Joint Commission on Clinical Investigations, the Institutional Review Board for the Johns Hopkins University School of Medicine.

Intervention development. We designed, implemented, and compared three intervention strategies for their impact on cardiovascular disease risk behaviors and outcomes. These included a behavioral model based on standard group methods with weekly sessions (SI), the same behavioral group model supplemented with a spiritual and church cultural component (SP), and a control group of non-spiritual, self-help interventions (SH). All interventions were developed through a partnership between community members and investigators, and were based on a community action and social marketing model developed originally by the Health and Religion Project of the Pawtucket Heart Health Program.[17]

We designed interventions at the individual level to enhance self-efficacy but implemented them through the churches in group sessions to assure strong support and incorporation into the social milieu of women of this age group.[18] Focus groups were held with churchgoing women from the African American community in Baltimore to determine what kinds of nutrition or physical activity interventions would be most appropriate. Based on these focus groups and additional in-depth interviews with 53 churchgoing women, we designed the interventions and tested the questionnaires to assess nutrition, physical activity, smoking cessation, and operational and feasibility aspects of program implementation. We incorporated into the interventions the themes, suggested session formats, and materials elicited and examined during the focus groups and in-depth interviews.

One church served as a pilot venue where we tested and refined the spiritual and church-culture component intervention over a 20-week period. In addition, we formed a Community Expert Panel to review and further refine the interventions and measurements. This group was comprised of four African American churchgoing women and two African American pastors from the community. None of the focus group, in-depth interview, or pilot church participants, or Community Expert Panel members, participated in the trial. This intensive community involvement in the design of the interventions assured cultural relevance of the interventions and study protocols and assisted ultimately in community "ownership" of resulting programs and dissemination of results.

Church recruitment and randomization. Churches that met eligibility criteria were identified from more than 700 inner city churches in Baltimore. Initial criteria included location in the urban core of Baltimore, a primarily African American congregation, and a known level of high interest and participation in local activities, such as revivals, conferences, and religious events. Once identified, churches were selected by the study's pastoral consultants and recruited from denominational strata. Baptists comprise the largest religious denomination in Baltimore and in African American communities in gen-

eral (as high as 62% in some areas of the southern US).[15] Therefore, we required that 50% of participating churches be Baptist and the remaining 50% be either independent or externally governed churches, such as Roman Catholic, Methodist, or Holiness. Eligible churches also had at least 80% African American congregations, average Sunday attendance of at least 150 individuals, and no currently active program in weight control, exercise, or smoking cessation for women aged 40 years or older. Because exact data on these variables are rarely formally maintained by a church, Project Joy staff and pastoral consultants determined eligibility through discussions with pastors and direct observation of Sunday church services prior to recruitment.

Once a church was determined to be eligible, we sent information on the proposed study to the pastor of the church. The principal investigator and project staff then met with the pastor and any key lay leaders to describe the project in detail, including the three interventions. To maintain the desired ratio of church denominations, envelopes were prepared for each denominational stratum to ensure appropriate representation in each of the three interventions. For the first 23 churches, if the pastor agreed to the project, he or she randomly selected an envelope to determine which intervention the church would offer. After selection of the intervention, the pastor and staff signed a *covenant* (a term more meaningful and acceptable to pastors than *agreement*) indicating their commitment to support Project Joy. Churches were enrolled sequentially until the desired sample size of 490 women was obtained.

We found that the first 23 pastors almost universally indicated a discomfort with the randomization process. They consistently wanted to be told at the beginning of the meeting to which intervention their church was assigned, even though they understood assignment was random. After realizing that the randomization protocol seriously hindered enrollment, we requested and received formal permission from the Institutional Review Board at Johns Hopkins to pre-randomize the church assignment and present the study to the pastor with full disclosure of the pre-randomization and description of the other interventions. Thus, for the last 15 churches, the staff described the project, all intervention contingencies, and the specific intervention to which that pastor's church had been randomly assigned. If the pastor agreed, the covenant was signed.

Participant recruitment. Lay leaders were designated to assist with the project by the pastor of each church after the first meeting. They were all African American females, usually known "influence leaders" who were highly respected in the church, and often included the pastor's wife. The number per church varied by church size and preference of the pastors and church staffs. Project staff met with these leaders to design participant recruitment strategies specific to the procedures of each church. After a one-month publicity phase during which church bulletin inserts advertised the program and featured tear-off forms with instructions for potential participants to give to the designated lay leaders, each church scheduled at least one Recruitment Sunday. Posters were displayed in the church and announcements were made from the pulpit by the pastor and lay leaders throughout the month for all three interventions. Choir rehearsals, Bible study groups, and other women's groups also received announcements. On Recruitment Sunday, announcements were made from the pulpit by both the pastor and the project staff, usually including the study's principal investigator, inviting all women aged 40 years and older to attend a recruitment meeting immediately following each service, where the intervention was presented in greater detail. Each interested woman completed an eligibility form at that time, and signed up for screening appointments. Women who did not schedule an appointment at the recruitment meeting, or who later heard about the project by word of mouth, were called later by project staff. All women who scheduled a screening appointment received a reminder card, map, instructions, and parking information.

Eligible participants were ages 40 years or older, were not pregnant or planning to become pregnant in the coming year, had not had a myocardial infarction or stroke in the past six months, had not felt any chest pain or angina requiring the use of nitroglycerine in the past six months, did not have cancer currently under treatment, were not undergoing renal dialysis, and were able to obtain permission to participate in the program from their physicians. Women who did not have a physician were referred to a federally funded community health center when necessary.

Despite aggressive and persistent recruitment and the offers of retreats and free risk factor screening, most women from churches randomized to the self-help contingency were not interested in the self-help intervention. Women were avidly interested in active sessions and expressed a strong desire to receive directed assistance. For this reason, the numbers recruited for the self-help contingency were lower. During recruitment in each church, even the numbers of women who merely stayed for the recruitment talk were much lower than for the two active contingencies. We attempted to increase numbers in the self-help comparison group by recruiting other church-going African American women through advertisements;

this attempt added a small number (16) of women who are included in the self-help group reference comparisons.

Standard behavioral intervention. Standard intervention churches held weekly sessions on nutrition and physical activity in their own facilities. Female African American health educators from the study staff taught the curriculum, standardized for the first 20 weeks of sessions (Figure), with the assistance of church lay leaders. Lay leaders were self-identified or assigned by the pastor and completed four hours of formal training by staff health educators on nutrition and fitness.

Each intervention session began with a weigh-in and group discussion, followed by a 30- to 45-minute nutrition education module that included a taste test or cooking demonstration. The sessions, based on social learning theory, were designed to enhance individual self-efficacy.[18] Each session included 30 minutes of moderate intensity aerobic activity, the nature of which varied by church; physical activities included brisk walking, water aerobics, or Tae Bo (Tae Kwan Do-dance-boxing). After the first 20 weeks, lay leaders offered weekly sessions, with health educators available

for support and additional information, for the remainder of the year.

Spiritual intervention. Churches offering the spiritual intervention received the same sessions as the standard intervention churches, with the addition of spiritual components and church contextual components designed by the Community Expert Panel and investigators. All weekly sessions incorporated group prayers and health messages enriched with scripture (see Figure). Physical activities included aerobics to gospel music or praise and worship dance. Telephone calls from lay leaders and word of mouth from other participants motivated attendance. Church bulletins included weekly session reminders and printed messages from Project Joy, called the *Joy of Health*, on healthy eating and physical activity, accompanied by salient scriptures. The pastors offered regular information on healthy eating and physical activity from tip sheets supplied by Project Joy and distributed a monthly health newsletter, called *From the Pastor's Desk*, to the congregation. Churches also participated in at least one event per year sponsored by Project Joy, such as walk-a-thons, faith and worship dance recitals, or fruit sales, all

Figure. Topics discussed in first 20 weekly sessions, standard and spiritual interventions, Project Joy, Baltimore, 1997–1999

Session	Nutrition topic	Exercise topic
1	The Food Guide Pyramid	Short-Term Benefits of Physical Activity
2	Fat Counting	Fitness Walking
3	Portion Size	Proper Footwear and Clothing for Exercise
4	Food Labeling	Exercise Buddies
5	Energy Balance	Principles of Exercise, Flexibility
6	Fruits	Heart Rate
7	Why We Eat	Exercise Intensity
8	Vegetables—Benefits	Health Benefits of Physical Activity
9	Vegetables—Preparation	Realistic Expectations from Exercise
10	Fats/Three-Month Review	Hot Weather Exercising
11	Meats	Safety Issues with Exercise
12	Meat Alternatives	Physical Activity That Can Become Exercise
13	Grains and Fiber	Other Aerobic Exercise
14	Dairy Foods	Distraction from Exercise
15	Salt/Sodium	Minor Injuries
16	Shop 'Til You Drop (the Fat)	Exercise Cues and Prompts
17	Dining Out	Exercise Interruptions
18	Breakfast, Lunch, and Snacks	Long-Term Maintenance of Exercise
19	Holiday Eating	Long-Term Maintenance of Exercise (continued)
20	Six-Month Evaluation	Vacation Ideas

We believe it is not possible to maintain a non-spiritual intervention within the African American church environment.

activities that exposed other church members to the health activities of Project Joy.

It should be noted that while the standard intervention was originally designed without spiritual elements, participating women in all SI-designated churches introduced spirituality into their sessions from the beginning, without staff assistance. Just as the pastors and lay leaders understood randomization but believed that in a world created and maintained by God nothing is random, the participating women did not believe there could be any church-based program that was not spiritual. They initiated sessions with prayer and selected their own relevant scriptures. Standard intervention participants also sought ways to include the entire church and the pastor. Ultimately, the standard and spiritual interventions operated almost identically.

Self-help control intervention. The self-help intervention was included as a control or reference contingency. It included materials from the American Heart Association on healthy eating and physical activity and information targeted to the participants' personal screening results. For example, pamphlets from the American Heart Association on smoking cessation or cholesterol were used for smokers or women with elevated blood cholesterol. Each participant received a gift-wrapped box with her name on it containing feedback about her personal screening results, a place to list her personal goals for the year, materials to allow self-monitoring, and the Project Joy, NIH, and YMCA educational materials and pamphlets. The behavioral goals for the standard and spiritual intervention groups were also included in the materials and were offered during the self-help retreat. In addition, the lay leaders for SH-designated churches received the same lay leader manual as the SI lay leaders, which contained not only content information and handouts for sessions but instructions on how to run sessions if churches chose to implement this part of the intervention. No further help was offered directly but a hot line number was available for consultation from the professional Project Joy health educators.

Baseline screening. All eligible participants in all interventions completed a baseline health assessment between March 1997 and March 1999 at the project offices, a non-clinical site. Before taking any baseline screening measurements, staff explained the program and screening procedures to all participants, and obtained informed consent for their participation.

Demographics and medical history. Standardized questionnaire items included employment status, years of education completed, household income, and current marital status. The project nurse reviewed each participant's self-reported medical history and probed for details on hypertension, hypercholesterolemia, diabetes, angina, myocardial infarction, congestive heart failure, cancer, arthritis, or other serious health problems. Current medications were verified by examination of the participant's medication containers brought to the first screening visit. Each participant's physician received a standardized form requesting medical clearance for participation.

Anthropometrics. Body weight was measured using a calibrated digital scale (SECA Alpha Model 770) with the participant wearing light indoor clothing and no shoes. Height was measured with a set square against a straight wall. Body mass index (BMI) was calculated as weight (kg) divided by height (m)^2. Bioelectrical impedance was used to assess percent total body fat using appropriate formulae,[19] based on resistance and reactance measurements (RJL Systems, BIA-101Q analyzer, Clinton, MI). Waist circumference was measured using guidelines of the National Obesity Expert Panel Report.[1]

Blood pressure and heart rate. Blood pressure was measured with a mercury sphygmomanometer according to American Heart Association guidelines.[20] All participants were seated quietly for at least five minutes prior to measurement, and had not ingested caffeine or smoked for at least 30 minutes prior to measurement. The average of three readings taken at least 30 minutes

apart was used to characterize blood pressure. Current hypertension was defined as having an average blood pressure ≥140/90 mmHg or taking current antihypertensive pharmacotherapy.

Blood lipid levels and glucose. Blood was obtained after the participants had fasted for 12 hours overnight. Total cholesterol, high-density lipoprotein (HDL) cholesterol, triglycerides (TG), and glucose were measured directly from plasma by the CDC-standardized Johns Hopkins Chemistry Laboratory. The coefficient of variation in this laboratory for total cholesterol measurement is less than 2%. Low-density lipoprotein (LDL) cholesterol was calculated using the Friedewald formula,[21] as no participants had TG ≥400 mg/dl. Diabetes was defined as having glucose ≥126 mg/dl or receiving current hyperglycemic (oral or insulin) therapy.

Dietary nutrient intake. The Block Food Questionnaire, a food frequency instrument (1995 scannable version), was administered to participants by a registered dietitian or research staff trained and supervised by the dietitian. All questionnaires were sent to Block Dietary Data Systems in Berkeley, California, for scanning and analysis, yielding individual nutrient intake measures of energy, total fat, sodium, and percent of energy from total fat.

Smoking and carbon monoxide. Smoking status was self-reported and verified by measured exhaled carbon monoxide (CO) using a Vitalograph EC50 CO monitor. The highest number that appeared on the monitor after exhalation into the monitor was recorded. If a participant was a stated non-smoker and the CO was measured ≥8 ppm, the test was repeated. If both measures were ≥8 ppm and the participant denied smoking, the participant was classified as a smoker.

Physical activity. Physical activity was assessed using the Yale Physical Activity Survey,[22] from which energy expenditure was calculated.

Retreats. Separate retreats for each church (16) were held after all participants from a given church had completed baseline screening and before the formal weekly sessions were initiated in the active intervention (SP and SI) churches. For the standard and spiritual intervention groups, the retreat included one 3-hour Friday evening event and a full day Saturday, while in the self-help intervention churches, the retreat included only a full Saturday. The retreats served as a kick-off for the program with

initial information and demonstrations on nutrition and physical activity, and as an incentive for participation, as this was an especially social event for all women participating in the project in a given church. Retreats were held at a local hotel and included: (a) motivational sessions; (b) introductory nutrition education sessions; (c) physical activity sessions, such as water aerobics, weight training, line dancing, and walking; and (d) an informational session in which participants received their individual results from the baseline screening and a registered nurse discussed CVD risk factors with the group. With the participant's permission, a copy of the same screening results was also mailed to each participant's physician. Nicotine patches were provided to smokers for the duration of the retreat so that all smokers would be able to remain smoke-free during the retreat.

Self-help church groups received the same materials and were oriented to the same goals as members of spiritual and standard church groups. All participants received the same information, along with personal boxes containing general risk factor information and information specific to each participant, as well as a leader's guide to allow all women to conduct sessions in their own churches. The spiritual retreats had sessions that were supplemented with scripture while the standard and self-help retreats did not include any scriptures. Interventions began in each church within one month after their retreat.

One year follow-up screening. After one year of intervention sessions, we recruited participants to repeat all measurements taken at baseline. Participants unwilling to return to the project offices were offered home or work-site visits, or church-site follow-up screenings inclusive of only the biological outcome measures. Incentives to complete follow-up were devised by the pastoral consultants and Community Expert Panel. These included tickets to a gospel play, a bus trip to a nearby outlet shopping, or gift certificates to local establishments, and were offered from the beginning of follow-up screening. Pastors from participating churches wrote letters to their own congregants encouraging completion of follow-up screening, and all pastors announced follow-up screening from the pulpit. Announcements were also placed in each church's bulletin. The only additional recruiting efforts employed were additional pastors' announcements and staff and lay leader telephone calls. Participants who completed follow-up screening received a mailed letter describing all baseline and follow-up results; a copy of this letter was also mailed to each participant's physician.

Intervention behavioral objectives. Goal behaviors included exercise of 30 minutes or more, 5 to 7 days per week; consumption of at least 5 servings of fruits and vegetables every day; fiber consumption of at least 25 g/day; fat consumption of 40 g/day or less; consumption of 1200 to 1800 dietary calories per day; and dietary sodium intake of 2400 mg/day or less. Smoking cessation was also a goal. Weight management was emphasized but achievement of a specific "ideal" weight was not emphasized. Women were encouraged to optimize dietary and physical activity and to achieve "reasonable" weight, or that level of body weight that they reached when they were meeting all of the above behavioral goals.

Statistics. We conducted all analyses with SAS software, version 7.0, using the intention-to-treat approach; participants who did not complete follow-up measures retained the same measurements at follow-up that they had during baseline assessment. We calculated simple frequencies and means, and used the chi square distribution for analyses of variance and contingency tables to compare baseline and follow-up measures within and between groups. We calculated changes in measures by subtracting the baseline measure from the follow-up measure. We used paired t-tests and analysis of variance to evaluate change in continuous variables, and McNemar's test to evaluate changes in categorical variables. We performed multiple linear and logistic regression analyses using the Generalized Estimating Equations (GEE)[23] approach to account for potential within-church clustering effects.

RESULTS

Of the first 55 churches identified by our pastoral consultants and community experts, 43 met all eligibility criteria. After introductory letters and packets were mailed to their pastors, 38 (88.4%) scheduled preliminary meetings and 18 (47.3%) enrolled. Of the 20 churches that did not enroll, 5 refused to participate during the period before pre-randomization; 2 were eliminated because no participants enrolled (both were self-help churches); 13 were eliminated because the church calendar was too full to allow expedient recruitment initiation (within six months); and 2 were eliminated by Project Joy for other reasons. Of the 16 churches enrolled, 8 were Baptist (50%), 3 were independent (that is, Holiness), and 5 were externally governed (Roman Catholic, United Methodist, and AME). Four churches offered the spiritual intervention, 5 churches offered the standard intervention, and the

remaining 7 churches offered self-help and included the 16 women recruited through advertising.

Of the 966 potential participants self-identified at the recruitment meetings, from the newsletter, or by word of mouth, 920 (95%) women were eligible. Of the eligible women, 702 (76%) scheduled appointments, and 559 (61%) were screened. Of those who completed baseline screening, 529 (58%) women enrolled. There were no differences in scheduling or enrollment rates between spiritual and standard intervention participants; however, self-help participants were significantly less likely to schedule appointments ($P = 0.001$), to keep appointments once scheduled ($P = 0.001$), or to enroll in the program ($P = 0.001$). Of those women who enrolled, 50.5% (267) were in the spiritual group, 35.5% (188) were in the standard group, and only 14.0% (74) were in the self-help group.

Baseline characteristics are shown in Table 1. Most participants had completed high school, three out of four were employed, slightly more than half had hypertension, and more than two out of five had arthritis. Demographic variables were generally similar among intervention groups.

Standard intervention participants attended an average of 6.4 (standard deviation ±6) professional health educator-led sessions, while spiritual intervention participants attended an average of 7.0 (standard deviation ± 6, $P = 0.235$). Attendance ranged from 65% at the first session to 26.1% at the last session across all churches, and on any given session attendance was one-third to one-half of overall participants. This varied slightly by church, but not by spiritual vs. standard intervention. None of the self-help churches held any sessions.

Fifty-six percent (294) of participants completed one-year follow-up biological measures and of these, 67.7% (199) completed all follow-up measures, including behavioral outcomes in diet and physical activity. Participants who completed follow-up were significantly older (54.7 ± 9 versus 50.9 ± 9, $P = 0.0001$), had lower incomes ($36,628 ± $21,100 versus $38,903 ± $24,000, $P = 0.3052$), were less likely to be currently employed (79% versus 67%, $P = 0.0036$), and attended more sessions (7.8 ± 6 versus 3.4 ± 4, $P = 0.0001$) than those who did not complete follow-up. Spiritual (159/267, 59.6%) and standard (106/188, 56.4%) intervention participants were significantly ($P = 0.0074$) more likely to return for follow-up than self-help (29/74, 39.2%) participants.

Changes in risk factors and behaviors. All follow-up and change measurements were based on intention-to-treat analyses. As noted, there were no real differences between the spiritual and standard interventions, so

Table 1. Self-reported baseline characteristics of African American women enrolled in Project Joy, Baltimore, 1997–1999, distributed by intervention group (N = 529)

Characteristic	Spiritual intervention (n = 267)		Standard intervention (n = 188)		Self-help intervention (n = 74)		P
	Mean	Standard deviation	Mean	Standard deviation	Mean	Standard deviation	
Age (years)...........................	53.6	±9	51.9	±9	53.9	±10	0.71
Annual household income (USD).........	42,070	±21,800	33,267	±21,600	33,945	±23,900	0.0004
Education completed (years)	13.5	±3	13.0	±2	13.7	±3	0.64
			Percent				
Completed high school education	92.9		90.4		93.2		0.60
Currently employed...................	75.4		74.0		75.7		0.94
Currently married	42.0		38.4		29.6		0.16
Currently smoking...................	13.9		16.5		9.5		0.33
Post-menopausal	69.0		66.9		66.2		0.85
Current hypertension	56.2		53.2		56.2		0.80
Current diabetes	13.1		9.6		20.3		0.07
History of arthritis...................	43.1		41.5		48.7		0.57
History of congestive heart failure........	2.6		4.3		1.4		0.40

NOTES: P for two-way ANOVA, GEE-adjusted for church effect comparing intervention groups for continuous variables; P for contingency table arrays and the χ^2 statistic comparing intervention groups for categorical variables.

results presented here show both SI and SP groups combined and compared with the self-help group (Table 2). Within the active intervention groups, there was a statistically significant change in a favorable direction for 11 of the 13 cardiovascular risk factor outcome measures, and a near significant change for energy expenditure, although the magnitude of the changes was modest. In the control group, there was a statistically significant change in only one of 13 outcomes: percent of energy of fat. Further, the magnitude of any other changes was far smaller than in the intervention group, with a gain in weight over the year. When only the women who returned for follow-up were used in the analyses, the magnitude of the changes in all variables in the active intervention groups was higher than when intention-to-treat analyses were used. The self-help group changes were even smaller than observed, with an average weight gain over the year of 2.1 pounds (standard deviation ± 1.3), more than twice that in the intention-to-treat analyses.

The group in the top decile for weight loss (average 20 pounds at one year) also achieved clinically meaningful, highly favorable changes in most other risk behaviors and outcomes; these changes, however, occurred only in the combined active intervention groups (Table 3). In the top decile of weight loss in the self-help group, changes in risk behaviors and outcomes were more modest, with an average weight loss at one year of only 7 pounds. All analyses of other changes within this group were underpowered, but Table 3 demonstrates the notable clinical differences between the self-help and active intervention groups.

The prevalence of achieving the behavioral goals of the intervention significantly improved from baseline to follow-up in the combined intervention group (Table 4), particularly in the top decile for weight loss where the increase in the proportion meeting behavioral goals mirrored the positive biological changes observed on Table 3. The proportion of the self-help group meeting behavioral goals at follow-up decreased or stayed exactly the same (for consumption of fruits and vegetables and dietary fiber consumption), or increased by an average of only 1% to 2% for meeting any of the goals. The greatest change among self-help participants was an absolute increase of 5.4% of participants who consumed ≤2.4 grams of sodium per day.

Multiple GEE church-adjusted logistic regression predicting the "most successful" participants, those in the

Table 2. Baseline levels and absolute changes in outcomes after one year participation in Project Joy study, Baltimore, 1997–2000, within and between combined active intervention and control groups (N = 529)

| Outcome | Combined standard and spiritual intervention groups (n = 455) | | | | | Self-help control group (n = 74) | | | | | |
| | Baseline | | Change | | | Baseline | | Change | | | |
	Mean	Standard deviation	Mean	Standard error of mean	Within group P	Mean	Standard deviation	Mean	Standard error of mean	Within group P	Between group P
Weight (pounds).......	191.6	±45	-1.1	±0.42	0.0089	184.9	±51	0.83	±0.52	0.1147	0.0008
BMI (kg/m²)...........	32.6	±7	-0.17	±0.07	0.0145	31.7	±8	0.14	±0.09	0.1157	0.0012
Waist (inches).........	39.5	±7	-0.66	±0.11	0.0001	38.8	±8	-0.007	±0.20	0.9729	0.0047
Body fat (percent)......	41.0	±6	-0.37	±0.11	0.0006	39.7	±7	-0.11	±0.10	0.2416	0.1886
SBP (mmHg)..........	135.0	±20	-1.6	±0.54	0.0037	136.0	±20	-0.95	±1.1	0.3812	0.4698
DBP (mmHg)	82.1	±10	-0.36	±0.29	0.2138	82.3	±11	0.22	±0.62	0.7289	0.4983
LDL-C (mg/dl)........	125.8	±35	-1.8	±0.87	0.0370	132.9	±37	-0.11	±1.6	0.9455	0.3686
HDL-C (mg/dl)	58.8	±16	0.13	±0.33	0.7019	58.2	±14	0.92	±0.70	0.1941	0.2831
Energy intake (kcal/day)	2077	±695	-117	±16	0.0001	2251	±868	-7	±32	0.8190	0.0038
Total fat (g/day)	91.8	±39	-8.1	±0.99	0.0001	101.3	±45	-2.3	±2.0	0.2374	0.0250
Energy from fat (percent)	39.2	±7	-1.7	±0.27	0.0001	40.0	±6	-1.2	±0.47	0.0116	0.5272
Sodium (mg/day).......	2692	±1008	-145	±25	0.0001	2973	±1212	-8	±37	0.8313	0.0167
Energy expenditure (kcal/day)	591	±473	38	±21	0.0654	479	±449	28.2	±45	0.5318	0.8592

NOTES: Significance of within group comparisons, P for intention-to-treat student's paired t-tests comparing baseline to one-year follow-up measurement. Significance of between group comparisons, P for intention-to-treat ANOVA, GEE-adjusted for church effect, comparing intervention groups.

BMI = body mass index
SBP = systolic blood pressure
DBP = diastolic blood pressure
LDL-C = low-density lipoprotein cholesterol
HDL-C = high-density lipoprotein cholesterol

top decile for weight loss, showed that the higher number of sessions attended (P <0.0001), older age (P = 0.03), higher baseline BMI (P <0.0001), and inclusion in the active intervention groups (P = 0.0014), were all significant independent predictors, while having diabetes (P = 0.24) and hypertension (P = 0.39), and religious denomination (P = 0.73), were not.

DISCUSSION

Effect of intervention. This study demonstrates the potentially important behavioral and biological risk modification effect of active church-based group interventions for African American women. We observed significantly improved anthropometric measures, blood pressure levels, diet and, to a lesser extent, physical activity at one year in the active intervention groups, although the magnitude of the effect was modest. Our overall findings are generally similar to previous church-based weight loss and dietary intervention programs. One group[14] increased the proportion of rural African American church members in North Carolina consuming at least five fruits and vegetables per day from 23% to 33%. The PATHWAYS study[8] showed a weight loss of 10.0 pounds and waist circumference decrement of 2.5 inches after 14 weeks of a church-based intervention, compared to a weight gain of 1.9 pounds and waist circumference decrement of 0.4 inches in a control group. Lighten Up, a church-based

Table 3. Mean baseline and change measurements at one year follow-up for top 10% in weight loss of Project Joy participants, distributed by intervention group, Baltimore (N = 53)

Measurement	Combined standard behavioral and spiritual intervention groups					Self-help control group				
	Baseline	Standard deviation	Change	Standard error of mean	P	Baseline	Standard deviation	Change	Standard error of mean	P
Weight (pounds)...	219.0	± 54	-19.8	± 2	0.0001	207.8	± 88	-7.0	± 1.7	0.0038
BMI (kg/m²).......	36.5	± 7.8	-3.3	± 0.3	0.0001	34.6	± 12	-1.2	± 0.28	0.0038
Waist (inches).....	43.3	± 7.7	-3.9	± 0.5	0.0001	42.1	± 11	-1.2	± 0.97	0.2616
Percent Body fat...	43.6	± 5.8	-2.5	± 0.51	0.0001	40.6	± 9	-0.5	± 0.38	0.2576
SBP (mmHg)......	138.0	± 17	-8.1	± 2	0.0005	139.4	± 12	-3.3	± 5.5	0.5688
DBP (mmHg)......	82.9	± 9	-4.4	± 1	0.0004	83.0	± 12	0.8	± 2.9	0.7805
LDL-C (mg/dl).....	122.0	± 34	-7.4	± 2.8	0.0126	134.8	± 45	-2.8	± 10.4	0.7990
HDL-C (mg/dl)	58.8	± 18	1.2	± 1	0.2390	65.3	± 10	-2.1	± 2.9	0.4875
Energy intake (kcal/day)	1918	± 616	-286	± 64	0.0001	2253	± 1111	21.5	± 72.7	0.7759
Total fat (g/day)....	83.2	± 33	-21.5	± 4	0.0001	105	± 53	-5.5	± 5.9	0.3874
Percent energy from fat	38.6	± 8	-6.0	± 1	0.0001	41.2	± 6	-4.4	± 2	0.1003
Sodium (mg/day) ...	2509	± 919	-300	± 93	0.0023	2646	± 1120	-41.4	± 136	0.7702
Energy expenditure (kcal/day)	524	± 357	230	± 117	0.0551	473	± 299	119	± 88	0.2187

NOTE: Within group comparisons; P for intention-to-treat student's paired t-tests, comparing baseline and one-year follow-up measures

lifestyle program,[24] showed an average 2.3-pound weight loss after 10 weeks. Another study[6] showed a 6.0 pound weight loss at eight months, six months after an 8-week weight control program of weekly diet and exercise sessions, and yet another[25] found a 4.2-pound weight loss one year after an 8-week church site program directed explicitly at weight control.

There are some important differences between our study and those of others. Follow-up for our study was longer than most, occurring one year after program initiation and 32 weeks after our health educators withdrew from the church. Further, most other studies have not focused on globally healthy lifestyles, but on a single behavioral goal, such as fruit and vegetable consumption or weight loss. The effect of our program overall, as well as the particularly large sustained impact on changes in multiple behaviors and biological risk factors in a small subgroup, is encouraging and supports the findings of other shorter, more focal studies.

It is unlikely that the observed effect in this study represents artifact or regression to the mean, as the self-help control group did not show benefits of this magni-

tude. Although the number of participants in the self-help control group was much smaller than we anticipated or than would have been ideal, we did find statistically significant differences between the active intervention group and the self-help control group for most outcome measures. Further, the absolute number of biological and behavioral risk factors that changed was much greater in the active intervention group than in the self-help control group. The fact that the number of sessions attended was strongly related to a beneficial outcome probably indicates that the most motivated women achieved the greatest benefits. The active interventions remained significantly and independently more likely to result in women achieving the greatest clinical benefit.

More importantly, 10% of participants in active church-based interventions achieved highly clinically significant improvements in CVD risk profiles one year after program initiation. The change in CVD risk in this top decile is of greater magnitude than has been shown in most prior studies in this high-risk population, and of a magnitude that is notable given the large group nature of the interventions. The fact that changes of this magni-

Table 4. Intention-to-treat outcome measures at one year for percentage of combined active intervention (SP and SI only) participants, and top 10% in weight loss participants

Goal outcome	Combined standard and spiritual interventions groups N = 455			Upper decile in weight loss N = 45		
	Baseline	Follow-up	P	Baseline	Follow-up	P
Exercise ≥30 minutes/day, ≥5 days/week.	11.1	12.0	0.4652	8.9	13.3	0.4142
Consume ≥5 servings of fruits and vegetables/day	38.2	44.6	0.0001	40.0	62.2	0.0075
Consume ≥25 g fiber/day	4.8	7.3	0.0278	4.4	11.1	0.1797
Consume ≤40 g fat/day	4.9	9.7	0.0001	6.8	27.3	0.0067
Consume 1200–1800 kcal/day	30.0	34.2	0.0262	34.1	45.5	0.2752
Consume ≤2.4 g sodium/day	44.4	50.3	0.0001	51.1	71.1	0.0027

NOTE: P from McNemar's test for difference in proportions between baseline and one-year follow-up

tude were existent in even 10% one year after program initiation is also important, as most studies find short-term effects without enduring sustainable impact.

Implementation issues. Prior studies have shown that churches are excellent sites for accessing people for community-based health promotion programs.[2,4-10,13,14] The current study confirms the interest of churchgoing women in active healthy lifestyle programs offered in the church, with a particularly strong interest in a spiritually based program. As noted, there were no differences in outcomes between the spiritual and standard intervention churches, despite the fact that all materials in the standard intervention were originally designed without spiritual elements. No attempt was made to include the entire church in the standard behavioral interventions, yet in the case of every church, the participating women incorporated a spiritual element from the first session of the retreat. Participants invented ingenious ways to involve the entire church and the pastor, initiated sessions with prayer, and sought relevant scriptures of their own selection. Some standard intervention churches even designated a lay leader to seek and integrate scriptures. Even in the spiritual intervention churches, women incorporated more spirituality than was originally included in the session materials and protocols. Ultimately, the spiritual and standard interventions operated almost identically, so it is not surprising they did not show any differences in outcomes.

Most women were unaware that Project Joy differed in form among the various churches in Baltimore, and churches generally were not in contact with one another. The first church started months before any others and was a standard intervention church. Spirituality was incorporated by the women from the very first group session. The chief programmatic concern expressed in post-intervention assessments in the standard intervention churches was that the materials were not spiritual enough. In every church at every juncture, women incorporated prayer and scripture into their weekly didactic sessions and added gospel music to their exercise sessions. Having had this experience with several hundred women, we believe it is not possible to maintain a non-spiritual intervention within the African American church environment. Finally, the degree to which a pastor was involved was not dependent on the role assigned to him or her, but was highly individualized. Even in many standard intervention churches, the pastor chose to incorporate the activities of Project Joy into the Sunday services and into the consciousness of the church.

Active versus self-help strategies. One important finding of this study is the almost total lack of interest in a self-help program. At each level of our recruitment process, pastors, churches, and women were least interested in the self-help intervention despite the fact that they received free screening with feedback, individualized intervention materials, and a retreat to promote healthy lifestyle. Women simply wanted the active intervention sessions at their churches. Even when the pastor agreed to participate in the self-help contingency, aggressive and persistent efforts to recruit individual women in church ser-

vices and by word of mouth were only modestly success-ful. Women consistently expressed an interest in having weekly sessions operated by knowledgeable professional leaders. They felt their peers were not qualified to lead intervention groups.

This finding appears to contradict previous work sug-gesting that volunteers are sufficient to run church-based health promotion programs.[26] Process data from atten-dance logs showed consistently that churches had lower weekly attendance after the professional health educators stopped leading the weekly sessions, in spite of the transfer to trained lay leaders. In our post-study focus groups and in-depth interviews, women indicated that this decline was due to a lack of confidence in the capabilities of peers whom they did not believe had the same expertise as the professional health educators. It was difficult for them also to shift their peer relationships with these women and to accept them as leaders, as they had all attended the ses-sions together. It is possible, however, that had the inter-ventions begun with trained lay volunteers, without partici-pants ever being exposed to the professional staff, that acceptance of volunteer lay leaders would have been greater. At the pastoral level, pastors were more interested in expert-led programs for their churches, also, because of greater confidence in professional support staff. Thus, while the study was designed to examine self-help as an intervention, our findings suggest, as have others, that edu-cation by itself is not sufficient to engage women in work-ing on healthy lifestyles, although there was some modest benefit accrued by women in this group.

Randomization. The unwillingness of pastors to take part in the randomization process was surprising, and one that may be embedded in the ethos of the church environment and specific individuals. While pre-ran-domization in the later recruited churches was not ideal from our research perspective, it was more acceptable to the pastors and yielded a lower refusal rate. Previous studies had shown churches to welcome the randomiza-tion process;[7] however, they were not in the context of offering a spiritual versus non-spiritual intervention, which almost certainly affected the willingness to be randomized. Pastors did not wish to be seen as having "determined" which intervention their churches would receive. This is based on their personal belief that "God guides their hands." Once informed of the spiritual intervention, they all preferred to have it and did not wish to participate without it. However, they were far more accepting of a non-spiritual intervention if their churches were randomly assigned to a program in

advance, stating their ability to attribute the pre-assign-ment to divine providence.

Attendance. Most women attended the retreat and were very excited to begin the program at that point. All churches began weekly intervention sessions within one month after the retreat, usually within one week, so we believe a time gap was not the reason for the drop in attendance. Process data suggest that women stopped coming because they did not see immediate results, simi-lar to the reasons they gave for not returning for follow-up screening. Telephone calls from staff health educators and social support from the pastor and church community was clearly not enough to motivate attendance. This should not be a surprise, as it is found in every other behavioral intervention reported in the literature, especially physical activity interventions. Our participants have suggested offering a choice of multiple days per week, offering ses-sions at night, and opening the program to the whole fam-ily. This was beyond what we had funding to do. Anecdo-tally, we found that the churches with the strongest support from the pastor's wife had the best attendance, while the churches with minimal support from the pastor's wife had the lowest attendance. Future studies will need to develop additional strategies to increase attendance.

Church "ownership" of program. Prior work has demon-strated the need to work in partnership with churches, not merely to impose the research agenda on the church.[2,7,12,27-29] In each church, we worked with the pastor and church leaders to train lay leaders and to give them the program materials outright, allowing each church to make the pro-gram its own in whatever form desired after the 20 weeks of health educator-managed sessions. Because of this own-ership building process, sessions following the 20 weeks varied by church. Some participants were more interested in nutrition and left the weekly sessions early to avoid the physical activity. One church was more interested in physi-cal activity, and wished to drop the nutrition portion alto-gether but did not. Pastoral commitment appeared to be an important factor in motivating continued participation; even more essential was a commitment to the project from the pastor's wife or another woman acting as a spiritual leader of the church. Although attendance by the original cohort for this study decreased after the first 20 weeks, the ownership building was quite successful. To date, eight of the nine active intervention churches are holding weekly sessions led by their own lay leaders. The pilot intervention church continues to meet weekly, more than four years after the inception of Project Joy.

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Follow-up. Rates for follow-up were lower than expected, although comparable to other church-based studies. For example, in one study 75% of the intervention group returned for follow-up while only 36% of the control group returned.[9] Pathways had 78% experimental group return, and 90% control group at 14 weeks.[8] Another had a 77% return rate two years out,[14] while still others had 41% return at eight months,[6] and 50% return at one year.[25] Data from our post-intervention focus groups and in-depth interviews, including some women who did not return for follow-up, suggested that the primary reason for not returning was participant failure to achieve the goals or biological outcomes within the context of the church, indicating a personal break with the covenant they had made in their spiritual lives. Virtually none of the pastor-designed incentives or pastoral entreaties to complete follow-up worked. This may be a problem unique to churchgoing women, but it does suggest that the women who did not return had a higher probability of having gained weight or some unfavorable measurable variable. However, even the conservative intention-to-treat analyses still showed significant changes in the desired direction.

Implications. Despite their relatively small impact in the active intervention groups, our church-based interventions attenuated the common increase in body weight shown to occur within as little as one year in some women, as was observed in the self-help control group.[30] These women, many of whom were post-menopausal, both lost weight and improved their diets, thus improving their lifestyle. The fact that this weight loss was accompanied by healthful behavior changes in nutrition suggests that there is an overall improvement in pro-health lifestyles in a group at very high risk for chronic diseases.

Conversely, many community studies have shown an intervention's impact on knowledge and self-reported behaviors but have not demonstrated any biological benefit. In the current study, the convergence of modest to significant dietary behavior change with favorable biological change suggests that community interventions at the level of the church, where there is continuing support and reinforcement, have a reasonable chance of influencing the health of participants. If the statistical findings of this study (that is, changes of this magnitude in the overall group accompanied by changes of the magnitude found in 10% of the group) were applied to the entire population of churchgoing African American women at risk for cardiovascular diseases, it is possible they could help shift the public health burden of disease in ways that more labor-intensive clinical interventions cannot. Our church-based interventions can reach more people and sustain effects longer through the continual reinforcement of community systems. If interventions of this nature were disseminated through large national organizations, such as the Congress of National Black Churches, for example, which represents various denominations with 65,000 churches and more than 20 million people, the public health impact could be quite considerable.[31]

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